

## REMARKS

This is responsive to the Office Action of May 2, 2007. Entry of this Amendment and reconsideration of the subject application in view thereof are respectfully requested.

### Status of Claims

Claim 11 is pending in this application. This claim has been amended to in response to the Examiner's claim objection. No new matter is added.

### Claim Objections

The Examiner has objected to Claim 11 for reciting "complementary sequence to said genes" in line 4 of the claim and required that this language be amended to recite:

--complementary sequences to said genes--. Applicant believes that this objection has been overcome in view of the amended claim 11 herein. Reconsideration is respectfully requested.

### Rejection Under 35 U.S.C. §112, Second Paragraph

Claim 11 has been rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the metes and bounds of the claim is indefinite because it is unclear to the Examiner whether the claimed oligonucleotide array "comprising" an array of multiple oligonucleotides may further comprise nucleotide sequences other than the specified multiple oligonucleotides. To overcome this rejection the Examiner suggests an amendment to claim 11 to recited --consisting of- in place of "comprising" in line 1 of claim 11. Applicant respectfully traverses this rejection and submits that the claim satisfies the requirements of 35 U.S.C. §112 for at least the reasons discussed below:

The phrase "comprising," transitioning from the preamble to the body of the claim, signals that the entire claim is open-ended. It is a term of art used in claim language which means that the named elements (in the instant case, "an array of multiple oligonucleotides") are essential, but other elements may be added and still form a construct within the scope of the claim. See MPEP § 2111.03. See also *Genentech, Inc., v. Chiron Corp.*, 112 F.3d 495 (Fed. Cir. 1997). It implements the principle that a claim is intended to provide a concise statement distinguishing the claimed invention from prior art; a claim is not a handbook for practice of the invention. *Smith & Nephew, Inc. v. Ethicon, Inc.*, 276 F.3d 1304 (Fed. Cir.

2001). Further, the definiteness of the language used must be analyzed not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one skilled in the pertinent art. *Solomon v. Kimberly Clark Corp.*, 55 USPQ2d 1279 (Fed. Cir. 2000). The statute is satisfied if a person skilled in the field of the invention would reasonably understand the claim when read in light of the specification. The § 112, second paragraph, demands no more. *Union Pac. Res. Co. v. Chesapeake Energy Corp.*, 236 F.3d 684 (Fed. Cir. 2001); *Credle v. Bond*, 30 USPQ2d 1911 (Fed. Cir. 1994).

Claim 11 recites multiple oligonucleotides that are essential and one of ordinary skill in the art would understand what is claimed when the claim is read in light of the specification. For purpose of completeness only, Applicant respectfully submits that breadth of a claim is not to be equated with indefiniteness. Thus, claim 11 reciting the transitional phrase “comprising,” is not indefinite.

Accordingly, Applicant respectfully requests reconsideration and removal of the rejection under 35 U.S.C. § 112, second paragraph.

#### Rejection Under 35 USC § 102

Claim 11 has been rejected under 35 U.S.C. § 102(b) as being anticipated by Chenchik et al., WO 98/53103 (“Chenchik”). This rejection is respectfully traversed.

Claim 11 requires, among other things, an array of multiple oligonucleotides with different base sequences fixed on to known and separate positions on a support substrate . . . and the multiple oligonucleotides are classified according to their gene functions.” In addition, the claim requires “the support substrate has fixation regions divided according to said classification, wherein the classification is (1) internal and external standard genes for proofreading, (2) stress-related genes related to heat shock protein and hormone genes that decreases under stress, (3) cytokine genes, (4) genes that induce cell death, (5) genes related to anti-inflammation and wound healing and genes related to cell growth inhibition, (6) transcription factor and signaling molecules related to immune response, (7) induction of cytokine, which causes cell injury, (8) transcription factor and signaling molecules related to growth inhibition, and (9) transcription factor and signaling molecules related to stress response.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Schering Corporation v. Geneva Pharmaceuticals, Inc.*, 339 F.3d 1373 (Fed. Cir. 2003). Identity of

invention requires that a prior reference disclose to one of ordinary skill in the art all elements and limitations of the patent claim. *Scripps Clinic v. Genentech*, 927 F.2d 1565, 1576 (Fed. Cir. 1991). Absence from the reference of any claimed element negates anticipation. *Kloster Speedsteel AB v. Crucible, Inc.*, 230 USPQ 81 (Fed. Cir. 1986). Inherent anticipation requires that the missing descriptive material is "necessarily present," not merely, probably or possibly present in the prior art reference. *In re Robertson*, 169 F.3d 743 (Fed. Cir. 1999). In general, a limitation or the entire claimed invention is inherent and in the public domain if it is the "natural result flowing from" the explicit disclosure of the prior art. *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 970 (Fed. Cir. 2001). To anticipate, the reference must also enable one of ordinary skill in the art to make and use the claimed invention. *In re Donohue*, 766 F.2d 531, (Fed. Cir. 1985).

Chenchik teaches human stress array and, in table 5, lists stress response regulators and effectors from a category of genes. However, Applicant respectfully submits that Chenchik fails to teach each of the limitations of Claim 11. Specifically, for example, Chenchik fails to teach that the support substrate has fixation regions divided according to a classification based on gene functions and that classification is (1) to (9) as recited in Claim 11. These limitations are absent or are not readily apparent from Chenchik.

The Examiner contends on page 6 of the Office Action that "Table 5 . . . fairly reads on the classification of gene functions (1)-(9) as set forth in lines 7-14 of claim 11 . . . Therefore . . . Chenchik et al. reads on a support substrate that has fixation regions divided according to the classification of gene functions as recited in claim 11." However, for a prior art reference to anticipate it must "necessarily," not merely "fairly" read on each and every element of the claimed invention. The Examiner has not pointed to any text in Chenchik showing that this reference necessarily teaches the missing claim limitations, i.e., the support substrate has fixation regions divided according to a classification based on gene functions" and that classification is (1) to (9) as recited in Claim 11. Thus, Chenchik fails to teach each and every limitation of claim 11, either expressly or inherently, which teaching is required for the reference to anticipate the claimed invention.

To anticipate, the cited reference must also enable one of ordinary skill in the art to make and use the claimed invention. In order to arrive at the claimed invention, the present inventors focused on specific categories of genes based on analytical experiments of human blood and found that arranging genes according to the categories of allows stresses to be readily assessed. This sort of enabling information is absent in Chenchik.

As such, given the strict identity required of the test for novelty, the Examiner has not established a *prima facie* case of anticipation in support of the rejection of claim 11. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the 35 U.S.C. 102(b) rejection of Claim 11.

**Conclusion**

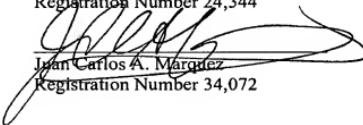
For the reasons presented above, the claim pending in the application are believed by Applicant to define patentable subject matter and should be passed to issue at the earliest possible time. A Notice of Allowance is requested.

If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the present application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,

---

Stanley P. Fisher  
Registration Number 24,344



Juan Carlos A. Marquez  
Registration Number 34,072

---

Nanda P.B.A. Kumar  
Registration Number 44,853

**REED SMITH LLP**  
3110 Fairview Park Drive, Suite 1400  
Falls Church, Virginia 22042  
(703) 641-4200  
August 30, 2007  
SPF/JCM/NK